

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>
<b>THIS DOCUMENT RELATES TO: ETHICON WAVE 4 CASES LISTED IN EXHIBIT A</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE  
OPINIONS AND TESTIMONY OF DR. NICOLE FLEISCHMANN, M.D.**

Plaintiffs hereby seek to exclude, or to limit in the Court's discretion, expert testimony proffered by Defendant Ethicon's ("Defendant") expert Nicole Fleischmann, M.D. ("Dr. Fleischmann"). In support of their motion, Plaintiffs state as follows:

**INTRODUCTION**

Dr. Fleischmann is a Urologist with a subspecialty in Pelvic Floor Medicine and Reconstructive Surgery, and Plaintiffs do not challenge her qualifications as such.<sup>1</sup> However, Dr. Fleischmann offers opinions in this case that are founded on unreliable methodology.<sup>2</sup> Dr. Fleischmann's experience in the field of Urology does not render all of her opinions admissible. The admissibility of Dr. Fleischmann's opinions is both contrary to law and presents a serious risk of confusing the issues and misleading the jury in this case.<sup>3</sup> As this Court has noted, "[j]ust

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<sup>1</sup> See Ex. B, (Gynecare Gynemesh PS/Prolift/Prolift +M Expert Report) at 1, Ex. C (TVT Retropubic Report) at 1, Ex. D. (TVT/TVT-O Report) at 1.

<sup>2</sup> See *Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.)

<sup>3</sup> See *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both

because an expert may be ‘qualified . . . by knowledge, skill, experience, training or education’ does not necessarily mean that the opinion that the expert offers is ‘the product of reliable principles and methods’ or that the expert ‘has reliably applied the principles and methods to the facts of this case.’”<sup>4</sup> Accordingly, Dr. Fleischmann should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

### **LEGAL STANDARD**

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.<sup>5</sup> The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge.<sup>6</sup>

### **ARGUMENT**

#### **I. Dr. Fleischmann’s opinions regarding the pore sizes of Defendant’s meshes are unreliable because she lacks the qualifications to offer these opinions.**

Dr. Fleischmann offers the opinion in her report that “the pore size of these meshes are appropriate.”<sup>7</sup> Dr. Fleischmann’s report states that this opinion is based on “medical literature and [her] surgical experience implanting these devices and treating patients who have had them

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powerful and quite misleading.”)(citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993)).

<sup>4</sup> *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, \*42-43 (S.D.W.V. 2013).

<sup>5</sup> *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005)(federal law governs admissibility of expert testimony).

<sup>6</sup> *See Daubert*, 509 U.S. at 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

<sup>7</sup> Ex. B, at 65-66 (Opinion #3); *see also* Ex. C, at 38 (Opinion #2: “The pore size of the mesh tape in TVT is sufficiently large...”); Ex. D, at 52 (Opinion #3: “...the pore size of the mesh tape in TVT and TVT-O is sufficiently large...”).

implanted.”<sup>8</sup> Dr. Fleischmann is not a materials expert and admitted at her deposition that she lacks expertise regarding mesh pore sizes.<sup>9</sup> Dr. Fleischmann’s deposition also revealed a lack of familiarity with literature discussing pore size significance.<sup>10</sup> Dr. Fleischmann conceded that she chose not to include literature in her reliance list or her report regarding how the mesh pores behave under tension.<sup>11</sup> Moreover, Dr. Fleishman’s statements about mesh pore size at her deposition are speculative and unreliable. For example, in response to a question about how the mesh pores behave inside the body, Dr. Fleischmann suggested that “I *could imagine* that if you pull tightly on a mesh the pore size will decrease.”<sup>12</sup> Dr. Fleischmann’s statement that she “could imagine” how the mesh may behave under certain conditions in the body is speculative and is not a reliable basis for an expert opinion.

Additionally, Dr. Fleischmann has not provided any basis for how her “personal experience” actually supports an opinion regarding the pore size of the Defendant’s mesh devices.<sup>13</sup> Neither *Daubert* nor the Federal Rules of Evidence allow for the admission of opinion evidence that is merely *ipse dixit* and there is too large of an analytical gap between Dr. Fleischmann’s personal experience and the pore size opinions she is putting forth.<sup>14</sup> Dr. Fleischmann’s opinion that the pore size of Defendant’s mesh devices are adequate is unreliable and should be excluded.

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<sup>8</sup> See Ex. B, at 66.

<sup>9</sup> Ex. E, at 103:17-23.

<sup>10</sup> *Id.* at 103:24-104: 19.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at 91:19-24 (emphasis added); see also *id.* at 92: 1-15.

<sup>13</sup> See Fed. R. Evid. 702 advisory committee’s note to 2000 amendment (“If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that expertise is reliably applied to the facts.”).

<sup>14</sup> *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (Trial Court “may conclude that there is...too great an analytical gap between the data and the opinion...”).

**II. Dr. Fleischmann’s opinion that Defendant’s mesh devices are “not defectively designed” must be excluded because it is unreliable and states a legal conclusion.**

**A. Dr. Fleischman lacks the qualifications to offer opinions on medical device design.**

Dr. Fleischmann suggests that the Gynemesh PS, Prolift, and Prolift +M devices are “not defectively designed” based on (1) the clinical outcomes of these devices, (2) her own surgical experience, (3) her interactions with colleagues, (4) her training, and (5) her instruction of other physicians.<sup>15</sup> Dr. Fleischmann’s opinion here is essentially that she believes these products are clinically safe and effective, and therefore, they must have been designed appropriately. However, Dr. Fleischmann is not a materials expert and does not have any experience designing medical devices.<sup>16</sup> This Court has previously excluded the mesh design opinions of medical experts who lack expertise in mesh product design.<sup>17</sup> The Court should likewise exclude Dr. Fleischmann’s opinion that the Defendant’s mesh devices are designed appropriately.

**B. Dr. Fleischman’s opinion that Defendant’s mesh devices are “not defective” must be excluded because it states an impermissible legal conclusion.**

This Court has consistently prohibited parties in these MDLs from offering opinion testimony that states a legal standard.<sup>18</sup> This Court has specifically held that “an expert may not offer expert testimony using ‘legal terms of art,’ such as ‘defective.’”<sup>19</sup> Dr. Fleischmann’s reports disregard this Court’s prior order and repeatedly use the term “defective” in regard to Ethicon’s devices. Dr. Fleischmann’s opinions that the TVT, TVT-O, Gynemesh PS, Prolift, and

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<sup>15</sup> Ex. B, at 65 (Opinion #2); *see also* Ex. C, at 52 (noting that the TVT and TVT-O “are not defectively designed.”); Ex. D, at 38 (noting that the TVT “is not defectively designed.”).

<sup>16</sup> *See* Ex. E, 103:17-23.

<sup>17</sup> *Winebarger v. Boston Sci. Corp.* No. 2:13-cv-28892 2015 U.S. Dist. LEXIS 53892, at \*101-\*104 (S.D. W. Va. Apr. 24, 2015) (excluding the opinions on mesh design of Defendants’ expert Dr. Culligan).

<sup>18</sup> *See* Dkt. No. 2696, at 10 (Memorandum Opinion and Order (Daubert Motion re: Dr. Nicole Fleischmann, M.D.)).

<sup>19</sup> *Id.*

Prolift +M devices are “not defectively designed” is a blatant violation of this Court’s prior orders and must be excluded.<sup>20</sup>

**III. The Court should exclude Dr. Fleischmann’s opinions regarding the Instructions for Use (“IFU”) for Defendants’ mesh devices.**

Plaintiffs previously moved to exclude Dr. Fleischman’s opinions regarding the TVT IFU in the Wave 1 cases.<sup>21</sup> On August 31, 2016, this Court entered a Memorandum Opinion and Order regarding the Wave 1 Motion and concluded that “Dr. Fleischmann does not possess the additional expertise to offer expert testimony about what an IFU should or should not include. Accordingly, Dr. Fleischmann’s expert testimony about these matters is excluded.”<sup>22</sup> The Court’s ruling here should be no different and Dr. Fleischmann’s opinions regarding the IFU for Defendants’ mesh devices should be excluded.

**CONCLUSION**

For reasons of the forgoing, the opinions of Dr. Fleischmann, as set forth herein, must be excluded as they do not meet the standard governing expert opinion set forth by federal law.

Date: April 13, 2017.

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<sup>20</sup> See Ex. B, at 65 (Opinion #2), Ex C, at 52, and Ex. D, at 38.

<sup>21</sup> See Dkt No.. 2051, at 13-16 (Memorandum in Support of Plaintiffs’ Motion to Exclude Certain Opinions and Testimony of Nicole Fleischmann, M.D.).

<sup>22</sup> Dkt. No. 2696, at 7.

**CERTIFICATE OF SERVICE**

I hereby certify that on April 13, 2017, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/ Edward A. Wallace